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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/363,748 07/30/99 WATKINS

C 108137.701

EXAMINER

HM12/0320

PEPPER HAMILTON LLP
GILBERTO M VILLACORTA
600 FOURTEENTH STREET N W
WASHINGTON DC 20005-2004

CRANE, L
ART UNIT PAPER NUMBER

1623
DATE MAILED:

03/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/363,748	Applicant(s) Watkins et al.
Examiner L. E. Crane	Group Art Unit 1623

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ---3--- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 01/12/01 (Amdt C, declaration & IDS)-----
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1-1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 39-50 ----- is/are pending in the application.
- Of the above claim(s) 47 ----- is/are withdrawn from consideration.
- ☐ Claim(s) ----- is/are allowed.
- ☒ Claim(s) 39-46 and 48-50 ----- is/are rejected.
- ☐ Claim(s) ----- is/are objected to.
- ☐ Claim(s) ----- are subject to restriction or election requirement.
- ☒ Claims x 1-38 have been ~~is~~ cancelled.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) ---12--- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☒ Other Copy of complete 1449 ref

Office Action Summary

Art Unit 1623

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

5 Claims **1-38** have been cancelled and new claims **39-50** were added as per the amendment filed January 12, 2001. A supplemental Information Disclosure Statement (IDS) also filed January 12, 2001 has been received and made of record as of the date of the instant Office action.

10 Claims **39-50** remain in the case.

Newly submitted claim **47** is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the "other" compounds listed in the noted claim are not all found in the cancelled claims **30-31** or in any other
15 claims now cancelled.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly claim **47** has been withdrawn from consideration as
20 being directed to a non-elected invention. See 37 C.F.R. §1.142(b) and MPEP §821.03.

Claims **39-46** and **48-50** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

Art Unit 1623

to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Inspection of the instant disclosure reveals no specific test data to support the generic limitations ("a neurological disorder," "a memory disorder," "memory disorder associated with aging") directed to the treatment of a disease condition or conditions, by the administration of uridine, cytidine, mixtures of uridine and cytidine, or any other uridine- or cytidine-containing binary or higher order mixtures of active or prodrug/precursor ingredients. For example, the noted claims read on the treatment of senile dementia, HIV-related dementia, and Alzheimer's disease, but the instant disclosure fails to provide any evidence that the instant method is effective in the treatment of any one of these disease conditions. Therefore, the instant disclosed exemplifications relevant to the instant claims are deemed to be entirely prospective and therefore lacking any enabling effect.

Applicant's arguments filed January 12, 2001 have been fully considered but they are not persuasive.

The instant amendment has not effectively addressed the original failure of the instant disclosure to provide an enabling disclosure. Applicant's argument alleges that the instant grounds of rejection is no longer applicable " ... because the new claims relate to a method of increasing cytidine in the brain by administration of uridine." Examiner respectfully disagrees, noting that the subject matter of new claim 39 is nearly identical in scope with the subject matter of original claim 1. Applicant is reminded that it is well known and established that "law requires that disclosure in an application shall

Art Unit 1623

inform those skilled in the art how to use appellant's alleged discovery, not how to find out how to use it for themselves." *In re Gardner et al.*, 166 USPQ 138 (CCPA 1970). Therefore, the instant grounds of rejection has been slightly amended in light of the newly submitted claims, but remains effectively the same and has been maintained for the reason noted.

Claims **39-46 and 48-50** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim **39** appears to be an incomplete method of treating claim because it fails to include a specific disease condition to be treated. This means that the limitations added in claims **41, 42 and 45** lack proper antecedent basis in claim **39**, and/or that claims **41, 42 and 45** are entirely superfluous because they fail to further limit any patentable feature of independent claim **39**.

Applicant's arguments with respect to claims **1-38** have been considered but are moot in view of the new grounds of rejection.

In claim **39**, the term "uridine or a precursor thereof" is directed to subject matter (or a precursor thereof) which as a functional term directed to chemical species lacks adequately defined metes and bounds. The same problem reoccurs in claim **50**, and a similar problem ("uridine or its precursor") occurs in claims **40 and 43-44**.

Art Unit 1623

Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

In claim 41 the term "a neurological disorder" is indefinite for failure to particularly point out the specific disease condition to be treated.

Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, dependent claim 41 recites the broad recitation "neurological disorder," and independent claim 39 recites "brain cytidine levels" which is a narrower statement of the range/limitation of the area of effect of the treatment being claimed.

Art Unit 1623

Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

5 In claims 42 and 50 the term "a memory disorder" is indefinite for failure to particularly point out the specific disease condition to be treated. A similar problem occurs in claim 45 ("memory disorder associated with aging").

Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

10 In claim 46 the term "a second compound" is indefinite for failure to define which compounds are included as ingredients and which compounds are not. The instant term does not exclude any other chemical compound, including obviously inappropriate embodiments such as arsenic oxide and strychnine.

15 Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

20 Claim 48 lists exemplifications of the "second compound" but then inappropriately expands the subject matter beyond the scope of claim 46 by including the term "or mixtures thereof." Therefore, claim 48 is lacking proper antecedent basis in claim 46, which is limited to a single "second compound" only. A very similar problem occurs in claim 49 ("or combinations thereof").

Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

Art Unit 1623

Claim 49 the terms "a uridine phosphorylase inhibitor," "[a] uridine secretion inhibiting compound," and "[a] uridine renal transport competitor" are indefinite functional terms because they refer to a single compound but fails to define which specific compounds are included and which compounds are not included within the metes and bounds of the instant claims.

Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in a patent granted on an application to another filed in the United States before the invention thereof by applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent."

Art Unit 1623

Claims 39-46 and 48-50 are rejected under 35 U.S.C. §102(b) or (e) as being anticipated by any one of PTO-892 references B, L, R, S, T, U, V, W, X, Y and Z.

Applicant is referred to each of the noted references wherein various uridine and uridine/cytidine mixtures and/or prodrugs mixtures are used to treat various neurological disease conditions including those of cerebral/brain origin including deterioration of memory.

Applicant's arguments filed January 12, 2001 have been fully considered but they are not persuasive.

Applicant states that the submission "... of new claims renders the rejection moot." Then applicant proceeds to argue the inapplicability of each of the cited references in light of the original claims. In the case of reference B applicant argues that this reference "is directed to the use of uridine as a growth promoter and a treatment of pathological aging and neuronal degeneration" (emphasis added) This argument is inconsistent with applicant's reliance in claim 41 on the overlapping term "neuronal disorder." In light of what appear to be conclusory summaries of these and the remaining references wherein no specific reference is made to which particular portion(s) of each references provides a proper basis for the stated conclusion, examiner concludes that applicant's arguments are not sufficiently detailed to be convincing.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See

Art Unit 1623

MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

5 A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS
FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE
DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS
FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS
FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL
AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY
PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE
10 ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY
EXTENSION FEE PURSUANT TO 37 C.F.R. §1.136(a) WILL BE
CALCULATED FROM THE MAILING DATE OF THE ADVISORY
ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR
RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF
15 THIS FINAL ACTION.

Papers related to this application may be submitted to Group
1600 via facsimile transmission(FAX). The transmission of such
papers must conform with the notice published in the Official Gazette
(1096 OG 30, November 15, 1989). The telephone numbers for the
20 FAX machines operated by Group 1600 are **(703) 308-4556** and
703-305-3592.

Any inquiry concerning this communication or earlier
communications from the examiner should be directed to Examiner L.
E. Crane whose telephone number is **703-308-4639**. The examiner
25 can normally be reached between 9:30 AM and 5:00 PM, Monday
through Friday.

Serial No. **09/363,748**

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Art Unit 1623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached at (703)-308-1701.

5 Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-**308-1235**.



10 LECrane:lec
03/16/01

GARY GEIST
SUPERVISORY PATENT EXAMINER
TECH CENTER 1600